Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

SNI National is Voluntarily recalling Kratom XL 4 Pack, Maeng Da Kratom 10 Pack, Max Kratom 20 Pack, and Bali Kratom 40 pack Due to Undeclared Drug Ingredients

Contact:
Consumer:
1-801-388-4690
Kratomrecall@gmail.com

Media:
1-801-388-4690

FOR IMMEDIATE RELEASE - March14, 2014 - SNI National is voluntarily recalling all Kratom products,including Kratom XL 4 Pack, Maeng Da Kratom 10 Pack, Max Kratom 20 Pack, and Bali Kratom 40 Pack, from distributors and retail locations. These products contain Kratom (Mitragyna Speciosa).

Kratom is a botanical that qualifies as a dietary ingredient under section 201(ff)(1) of the Federal Food, Drug, and Cosmetic Act . When marketed as a dietary ingredient, FDA considers kratom to be a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Furthermore, scientific literature discloses serious concerns regarding the toxicity of Kratom in multiple organ systems. Consumption of Kratom can lead to a number of health impacts, including respiratory depression, nervousness, agitation, aggression, sleeplessness, hallucinations, delusions, tremors, loss of libido, constipation, skin hyperpigmentation, nausea, vomiting, and severe withdrawal signs and symptoms.

The recall was initiated after the US Food and Drug Administration discovered that the product was distributed as a dietary supplement when, in fact, the primary ingredient did not fall under the Federal Food, Drug, and Cosmetic Act as having all the information necessary to deem it as a safe ingredient.

SNI National has to date not received any complaints or been made aware of any illness or adverse effects stemming from the sale of these products.

SNI National did not manufacture the products in question, but did re-package and re-label it for sale to wholesalers and distributors who further distributed the products.

The products are packaged in clamshell, zip sealed packets and green pill bottles, 4, 10, 20, and 40 count. The products can be identified by their bright green packaging and label which states that it contains Kratom. The products were sold to wholesale distributors in the following states: Alabama, California, Illinois, Missouri, Kentucky, Florida, Oklahoma, Idaho, Colorado, Wisconsin, Massachusetts, and Ohio. The products were further distributed by those entities. SNI National has completely terminated distribution.

SNI National is notifying its distributors and customers by Phone Call or Email, and is arranging for immediate return of all recalled products. Consumers, Distributors and retailers that have purchased or are selling these products should discontinue use or distributing them and return them to place of purchase, or discard them.

Consumers with questions regarding this recall can contact SNI National at (1-801-388-4690) or -**Kratomrecall@gmail.com** Monday-Friday 10:00 am to 2:00 pm Mountain Standard Time.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: **www.fda.gov/medwatch/report.htm**
- **Regular Mail or Fax**: Download form **www.fda.gov/MedWatch/getforms.htm** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.